

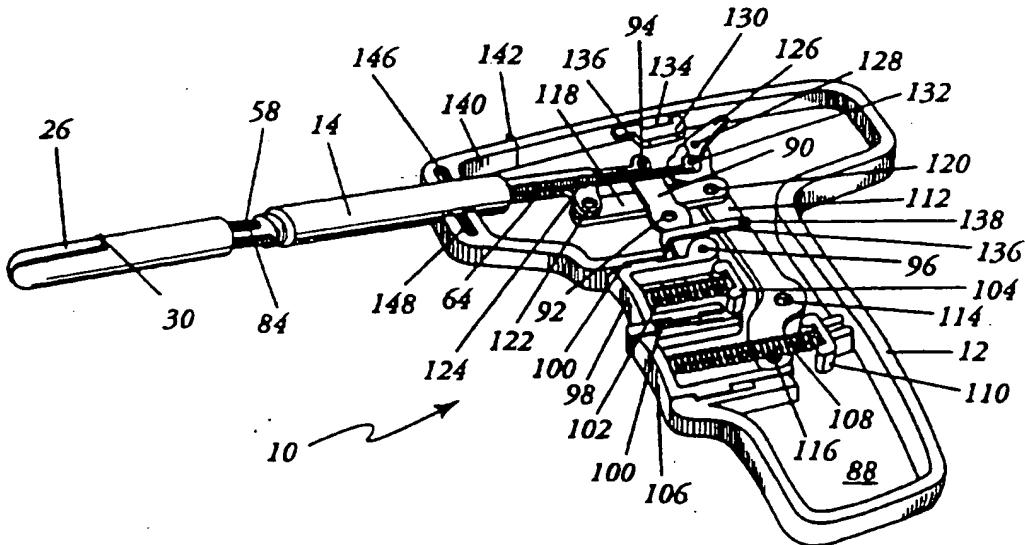


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(54) Title: LOW PROFILE TOOL FOR APPLYING SPRING ACTION LIGATION CLIPS



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DESCRIPTIONLOW PROFILE TOOL FOR APPLYING SPRING
ACTION LIGATION CLIPS5 TECHNICAL FIELD

The present invention relates generally to mechanical devices used in surgical procedures to obtain ligation or hemostasis, and more particularly, to low profile tools that can apply a pre-formed, spring loaded ligation clip used 10 during surgery to clamp around a vessel or duct, such as the cystic duct, and thereby obtain ligation.

BACKGROUND ART

15 It will be appreciated by those skilled in the art that the use of ligation clips to control bleeding during surgical procedures is well known. As described, for example, in U.S. Patent Nos. 4,976,722 and 4,979,950, prior art clips are generally formed of metal wire, usually a titanium alloy, having a "U-shaped" rectangular cross-section. Such prior 20 art clips often include a grooved pattern machined into the inner or clamping surfaces of the clip, in an attempt to enhance the ability of the clip to remain in position after it is closed around the vessel. Application of the clip to the vessel is normally effected by means of a crushing action produced by a clip applier, such as that disclosed in U.S. 25 Patent No. 5,030,226. Such crushing actions, of course, permanently deform the clips, making them difficult to remove or re-position.

30 Prior art surgical ligation clips have several inherent problems. For example, the force applied by the clip to the vessel can be variable and inconsistent from one clip to the next, because of the variation in crushing force applied to the clip by the user. Further, prior art clips have a tendency to slip off the end of the blood vessel stub (i.e., 35 perpendicular to the axis of the vessel) to which it has been applied, because of the low coefficient of friction associated with the clip, and lack of adequate restraining force provided by the clip. Because of this, separation of

the clip from the vessel to which it has been applied, after the wound has been closed, is not uncommon. A related problem found in the prior art is the fact that the ligating or restraining force offered by the crushed clip varies along the length of the clip, decreasing toward the open end. Thus, the section of the vessel near the open end of the clip can be inadequately ligated.

It is also common in the prior art to actually form and crush the clip only at the time of its application to the targeted blood vessel. It is often required that vessels of 4 mm and larger diameter be ligated. Because most clips of the prior art have no spring action it is required that the inside clearance dimension of the clip, prior to crushing, be larger than the vessel. This does not lend itself to clip applier designs that will pass through small 5 mm trocars. Accordingly, the clip applier mechanism of the prior art must be relatively large and cumbersome. This is a particular problem in laparoscopic procedures, during which both the clip and clip applier must be inserted through a trocar placed through the patient's external tissues and into the surgical field. Thus, prior art ligation clip applicators used in laparoscopic procedures universally consist of a 10 mm diameter clip applier that can fit only through a trocar having a 10 to 11 mm diameter entry port. Because one goal of laparoscopic surgery is to minimize the size of the entry wound, a surgical ligation clip and clip applier that can be used within a 5 mm diameter trocar port is highly desirable.

To address these problems, a new and improved surgical clip was designed, as illustrated in Fig.'s 1 and 2 and in U.S. Patent Application Serial No. 08/111,634 filed on August 25, 1993. The improved clip has a vessel clamping arm, a vessel support member, and at least one tension coil integrally joining the arm and support member. The clip is pre-formed so that in its equilibrium state, it can be easily placed within the surgical field, including through an endoscopic trocar port with as little as a five millimeter

diameter. After the clip is placed proximate the blood vessel or duct to be clamped, the clamping arm is moved from its equilibrium position to a position under higher tension, allowing positioning of the vessel between the arm and support member. When correct placement and positioning is achieved, the arm is released and, as the arm tends to move back towards its equilibrium position, it clamps the vessel between the arm's curved lower surface and the supporting upper surface of the vessel support member.

To enhance the performance of the tension coil(s), the vessel support member includes first and second arms, one of which terminates in a loop section. Minimal cross-sectional area of the clip is achieved by substantially longitudinally aligning the vessel support member, the clamping arm, the loop section, and the tension coil.

The clamping arm is pre-formed into an equilibrium that generally aligns with the horizontal plan of the support member. A second embodiment of the clip pre-loads the clamping arm into a relaxed position where the free end of the arm rests against the upper surface of the support member.

Unfortunately, several problems are encountered in applying this novel pre-formed, spring-action ligating clip on to a vessel through a 5 mm trocar port. First, the nominal 5 mm cross section of the clip that is inserted through the trocar places severe design restrictions on any applier mechanism. Traditional "crush type" clips require a crusher and anvil type applier mechanism which is too large to pass through a 5 mm trocar. Second, care must be taken so that the elastic limit of the spring material is not exceeded when the clip is opened up so that it can be placed over the vessel diameter. For titanium wire of diameter 0.75 mm, for example, lifting the distal end of the center leg of the spring much above 2 mm will exceed the elastic limit.

What is needed, then, is a clip applier tool that be used to place a pre-formed, spring action ligation clip

around a large diameter vessel without permanently deforming or weakening the clip, one that will compress, without crushing, the vessel, and yet be small enough to use in through a 5mm trocar.

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DISCLOSURE OF THE INVENTION

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The clip applier of the current invention solves the problems of prior art tools by incorporating a pre-clamp mechanism, the function of which is to pre-clamp the vessel to be ligated to a dimension such that the center leg of the spring of the ligation clip need be lifted only slightly. In this manner the spring clip can be slid over the smaller pre-clamped dimension. This insures that the clip spring material will remain within its elastic limit while allowing the tool to maintain a low profile for use in endoscopic surgery, even on large diameter vessels.

Fig. 1 is a perspective view in a somewhat schematic form of the device of the present invention.

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Fig. 2a illustrates in perspective the clips of the present invention within the cartridge of the device.

Fig. 2b illustrates a perspective view of a clip for which the applicator of the present invention is designed.

Fig. 2c is a cross section of the clip of Fig. 2b along the line C-C of Fig. 2b.

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Fig. 2d is a side view of the clip shown in Fig. 2b with the clip opened.

Fig. 3 shows a perspective view of the device of the present invention.

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Figs. 4a, 4b and 4c show side, top and end views of the device of the present invention in the at rest position.

Figs. 5a, 5b and 5c show side, top and end views respectively of the device of the present invention with the clip assembly advanced to the ready position.

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Figs. 6a, 6b and 6c show side, top and end views respectively of the device of the present invention with the pre-clamp arm opened.

Figs. 7a and 7b show side and top views respectively of the device with the pre-clamp arm pressing a vein and the clip opened for engagement with the vein.

5 Figs. 8a, 8b and 8c show the side, top and end views respectively of the device of the present invention with the pre-clamp arm closed and the ligation clip opened.

Figs. 9a, 9b and 9c show the side, top and end views of the device of the present invention in the position as occurs immediately following the position as shown in Figs. 8.

10 Figs. 10a, 10b and 10c show side, top and end views of the device of the present invention with the clip assembly extending beyond the end of the sleeve and the wings of the device releasing the clip.

15 Fig. 11 shows a cross section of the device of the present invention along the length of the trunk.

Fig. 12 shows a cross section of the device of the present invention taken to the left of the trunk.

20 Figs. 13a and 13b show a mechanism that can be incorporated in the device of the present invention to control advance of the clips into the ready position in the clip carriage.

BEST MODE FOR CARRYING OUT THE INVENTION

25 Referring now to Fig. 1, there is shown generally the preferred embodiment of the present clip applier. The device is indicated generally by the numeral 10. The device 10 includes the pistol grip 12 and an applicator sleeve 14. The applicator sleeve 14 contains a number of ligation clips 16 all in stacked relation and held in position in the manner hereinafter described. The ligation clips 16 are stacked generally in the trunk portion of the applicator sleeve 14 extend from the end of the sleeve 14 that is connected to the pistol grip 12 toward the proximate end 18 of the device 10.

30 Fig. 2b shows the shape and construction of a typical clip which the device 10 of the present invention is designed to apply during surgical procedures. The clip 16 is formed

generally of a wire type material, preferably round in cross section and having base 20 and pressure arm 22. The base 20 of this particular clip is an elongated U-shaped structure and pressure arm 22 overlies the base 20 and is positioned directly above the channel of the "U" formed between the two legs of the U-shaped base 20. Base 20 and the pressure arm 22 are connected at their distal end 24. When the ligation clip 16 is in an at rest position, the pressure arm 22 directly overlies the channel between the two legs of the U-shaped base 20. However, the pressure arm 22 can be rotated about the point of connection between the pressure arm 22 and the base end 20 at the distal end 24 to open the clip. When the clip is opened, the pressure arm 22 is pivoted about the connection point between pressure arm 22 and base 20. The connection between base 20 and pressure arm 22 is a spring type connection; however, that tends to bias the pressure arm 22 back into the "at rest" position as described previously. Thus, the ligation clip 16 may be opened by separating the pressure arm 22 from the base 20. That separation occurs when the base is held in position and the pressure arm 22 is forced away from the base 20 (as in the illustration shown in Fig. 2d). Pressure is applied to pressure arm 22 to force it to rotate clockwise about the pivotal connection at distal end 24 between base 20 and pressure arm 22. However, when the pressure is released from pressure arm 22, pressure arm 22 will rotate about the connection point between pressure arm 22 and base 20 at distal end 24 in a counter clockwise position back into the at rest position.

When the ligation clip is applied to a blood vessel or artery, the pressure arm 22 is "opened" from the base 20. The clip is inserted over the blood vessel so that the blood vessel traverses generally perpendicularly to the direction of the legs of the U-shaped base 20 over the top of the base 20 and beneath the pressure arm 22. When the force that causes the pressure arm 22 to open from the base 20 is released, the pressure arm 22 captures the blood vessel

between the underside of the pressure arm 22 and the top of the base 20 to compress the blood vessel and close it.

Referring now to Fig. 3, at the proximal end 18 of the device 10, there is shown generally a pre-clamp arm 26. Pre-clamp arm 26 can also be seen in Figs. 6a and 7a. Figs. 4a-10c all show various views and positions of the mechanism at the proximal end 18 of the device 10.

Referring now to Figs. 4a, b, and c, the device 10 is shown in the at rest position. In the at rest position, a clip carrier/activator assembly shown generally within the envelope 28 (Fig. 4a) is retracted within the application sleeve 14. For purposes of this description, the preferred embodiment will be referred to as it is oriented in the drawings. Clearly, if the device 10 was pointed in the opposite direction, the references to right and left would be reversed. The invention will be described with the understanding that the proximal end of the invention and of the applicator sleeve are to the left, and the distal end of the invention and the elements of it are to the right. Thus, the clip carrier/activator assembly 28 is in its extreme most right position when the device 10 is at rest.

The applicator sleeve 14 in the preferred embodiment has the shape of an elongated tube with a step down 30 formed in its proximal. While the applicator sleeve 14, in the preferred embodiment, is generally described as tubular and circular in cross section throughout the majority of its length, other cross-sectional shapes could be employed. The applicator sleeve has fingers 32 curled over the step down portion 30 of its proximal end. The pre-clamp arm 26 sits in the step down portion 30 of the applicator sleeve and fits within the envelope defined by the outer perimeter of the applicator sleeve 14 if that outer perimeter were extended beyond the left most tip of the device 10.

The pre-clamp arm 26 is elongated and, in the preferred embodiment, has an elongated slot 34 defined by the two side arms 36, 36'. Depending nose 38 is provided at the left end

of the pre-clamp arm 14 and connector extension 40 is formed with the pre-clamp arm 14 at its right end. Connector extension 40 has a hole 42 through it and is formed with a camming surface 44 in the bottom right portion thereof.

5 A carrier arm 46 extends from the applicator sleeve 14 beyond the step down portion 30 toward the proximal end of the device. The carrier arm 46 may be U-shaped in cross section or any other convenient configuration. In the preferred embodiment, the carrier arm 46 is U-shaped and has a base 48 and upwardly projecting legs 50. A pin 52 extends through hole 42 and through holes in the legs 50 to connect the pre-clamp arm 14 to the carrier arm 46. The carrier arm 46 has a step up 54 along the base 48 and located beneath the camming surface 44. A spring 56 is connected to the extension arm 46 and the bottom of the pre-clamp arm 14, directly to the left of the pivot point of connection pin 52. The spring 56 is biased such that it tends to pressure the pre-clamp arm 14 for clockwise movement about the pivot point 52.

20 Extending through the length of the applicator sleeve 14 along the upper side thereof is push rod 58. A ramp 60 is formed in the left end of push rod 58, and when the device is at rest, the push rod 58 is pushed to the left as can be seen in Fig. 4a. When push rod 58 is extended to its left most extreme position, the camming surface 44 rides over the ramp 60, forcing the pre-clamp arm 14 to rotate about the pivot point 52 in a counter clockwise direction into the closed position as shown in Fig. 4a. The pressure of the camming surface 44 riding over the ramp 60 and forcing the counter clockwise rotation of the pre-clamp arm 14 about the pivot point 52 overcomes the pressure of spring 56 to hold the pre-clamp arm in a "closed" position. In the "closed" position, the depending nose 38 extends down and over the extreme left end of the applicator sleeve 14.

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35 Pre-clamp arm 26 does not move length-wise relative to the length of the applicator sleeve 14, its only movement is

to pivot about the pin 52 being urged by spring 56 in a clockwise rotation to an open position when a push rod 58 is retracted toward the distal end of the device and being rotated counter clockwise about pin 52 to the closed position when the push rod 58 is advanced toward the proximate end of the device 10 and the camming surface 44 is forced to ride over the ramp 60.

In operation, the purpose of the pre-clamp arm 26 is to fit over a blood vessel or artery 62 (See Fig. 6a) and to flatten the vein so that it will be dimensionally sized to fit within the mouth of ligation clip 16 when pressure arm 22 is rotated in a counter clockwise direction to open the clip.

The ligation clip carrier/activator assembly 28 will now be described. In the at rest position, the ligation clip carrier/activator assembly 28 is retracted into the applicator sleeve 14 toward the distal end of the device as is shown in Fig. 4a. In the at rest position, device 10 is inserted through a trocar for use in a surgical procedure. Once the device 10 is inserted through a trocar into a body cavity, the clip carrier/activator assembly 28 is advanced to the ready position shown in Fig. 5a. The assembly 28 is captured on the proximal end of the device beneath the fingers 32. The assembly 28 includes clip carriage 64 and wings 66. The clip carriage 64 is an elongated element that fits within the applicator sleeve 14 and is telescopically moveable within the applicator sleeve 14. The clip carriage 64 also extends beneath the wings 66 as can be seen in Fig. 10a and 10b.

The ligation clips 16 are stacked within the clip carriage 64 with the distal end 24 of each clip aligned to the right as is seen in Fig. 2a. The trunk 68 of the clip carriage 64 is that portion of the clip carriage to the right of the assembly 28 as shown in Fig. 4a. The cross section of the trunk 68 of the clip carriage 64 is shown in Fig. 11. As can be seen from Fig. 11, the cross section of the trunk

5 68 is shaped to mate with the cross section of the ligation
clips 16 so that the ligation clips 16 will be held in
stacked alignment through the length of the trunk 68. A
plate and spring (not shown) are incorporated in the extreme
right end of the trunk 68 of the clip carriage 64 to apply
pressure against the distal end 24 of the clip in the extreme
right location of the device 10. The spring applies force
against the plate to pressure the clips toward the proximal
end of the device. Thus, after each clip is applied to a
10 vein, another clip is forced into a ready position for
application to another vein.

In the region of the clip carrier/activator assembly 28 (see Fig. 4a), the clip carriage has a modified cross section. The general shape of the cross section of the clip carriage 64 in the region of the clip carrier/activator assembly 28 is shown in Fig. 12. As can be seen there, clip carriage 64 has a substantially semi-circular outer perimeter (the outer perimeter is of a shape to mate with the shape of the inner surface of the channel through the applicator sleeve 14), and the shape of the interior portion of the clip carriage 64 at this point is designed to mate with the lower portion of the cross sectional shape of the ligation clip 16. However, beneath the channel formed by the two legs of the U-shaped base 20 of the clip 16 is a channel to house the ligation clip opening assembly. At this cross-sectional point of the device, above the base portion of the clip carriage 64 are located the wings 66. Wings 66 have an elongated dimple 72 of a shape to mate with the upper and outer perimeter of the ligation clip 16. Because the wings 66 are held beneath the fingers 32, the elongated dimple 72 allows the wings to hold the clip in place against the pressure necessary to open the clip in the fashion that will be disclosed herein.

35 The ligation clip opening assembly housed in the bottom most portion of the clip carriage 64 includes a depressor 74. The depressor 74 is generally pencil shaped, approximately

the length of the channel between the two legs of the base 20 of the ligation clip 16 and of a cross sectional profile of a size that will allow at least a portion of the depressor 74 to extend through the channel between the two legs of the base 20 of the ligation clip 16. The depressor 74 is pivotally connected at 76 at its proximal end to the upwardly projecting side walls of the clip carriage 64 and is permitted limited rotation about its pivotal connection 76. When the depressor 74 is in the at rest position, it lies flat along the base 78 of the clip carriage 64. A stop protrusion 80 is located on the depressor 74 to the left of the pivotal connection 76 to limit the rotation of the depressor 74. The depressor 74, from its at rest position, can only rotate in a counter clockwise direction and is limited in its movement because the stop protrusion 80 will engage the base 78 of the carriage assembly 64 after a limited counter clockwise rotation.

The depressor 74 has a cam surface 82 at its distal end. The cam surface 82 is in contact with the proximal end of the clip actuation push rod 84. The clip actuation push rod 84 is an elongated rod that fits within a channel in the base of the clip carriage 64 and is allowed to move to and fro within that channel from the at rest position shown in Fig. 6a to the trigger position shown in Fig. 7a and back to the at rest position of Fig. 6a. When the clip actuation push rod 84 is advanced to the left into the trigger position shown in Fig. 7a, the cam surface 82 of the depressor 74 rides up over the end of the clip actuation push rod 84 to rotate the depressor in a counter clockwise position. The distal end of the depressor protrudes into the channel between the two legs of the base 20 of the ligation clip 16 against the under side of the pressure arm 22 of the clip and forces the clip into the open position shown in Fig. 2d and in Fig. 7a. As the ligation clip 16 is being opened by the action of the depressor 74 against the pressure arm 22 of the clip, the entire clip carriage assembly is advanced toward

the proximal end of the device 10 in relationship to the applicator sleeve 14 so that the clip will capture the vessel 62 that has been flattened by the action of the pre-clamp arm 26. The vessel will then be captured between the upper surface of the base 20 of the ligation clip 16 and the lower surface of the pressure arm 22 of the ligation clip 16 and the clip actuation push rod 84 can be retracted toward the distal end of the device, allowing the depressor 74 to rotate back into the at rest position and release the pressure arm 22 to capture and close the vessel 62.

The next step in the procedure is to advance the clip carriage assembly 64 relative to the applicator sleeve 14 beyond the proximal end of the applicator sleeve 14 (See Figs. 10a and b). The wings 66 are connected to the clip carriage 64 by ribbon springs 86. The ribbon springs 86 are loaded to pressure the wings 66 to fan away from each other in the manner shown in Fig. 10b. The wings 66 will remain in parallel relationship so long as they are held within the applicator sleeve 14; however, once the wings 66 extend beyond the proximal end of the applicator sleeve 14, they are free to follow the pressure of the ribbon springs 86 and fan away from each other. The opening of the wings 66 releases the clip from the restraint of the elongated dimple 72 and thus the clip 16 is released from the device. The proximal tip of the device can be tipped slightly to allow the ligation clip 16 to clear the device 10 as the clip 16 holds onto the vessel 62 in the clamped position. At this point, the clip carriage assembly is retracted toward the distal end of the device relative to the applicator sleeve 14, the wings are returned within the confines of the applicator sleeve 14, another clip is released to advance to the ready position and the procedure can be performed again.

--- The mechanism for activating the pre-clamp arm and the clip assembly will now be described. Referring to Fig. 3, a cut away portion of the applicator sleeve shows the push rod 58 and the clip actuation push rod 84. The pistol grip

12 is shown with the cover removed so that the operation of the device can be described. The housing 88 of the pistol grip 12 can be constructed of any convenient sturdy material. Within the housing 88 of the pistol grip 12 is a pre-clamp push rod lever 90 which is hinged at 92 via a pin connected to a housing 88. The pre-clamp push rod lever 90 has opposing ends, one end 94 pivotally connected to the distal end of push rod 58 and the opposite end connected at pivot point 96 to the trigger 98. The trigger 98 fits within slots 100, 100' which allows the trigger 98 to traverse back and forth within the slots 100, 100' in response to pressure on the trigger by the user of the device 10. The return spring 102 is an expansion spring connected at one end against a stop 104 and at the other end against the inside of the trigger 98. Thus, when a user of the device applies pressure to the trigger 98 to force the trigger 98 to move to the right within the slots 100, 100'. The trigger 98 will return to its at rest position (its position to the extreme left within the device shown in Fig. 3) when the pressure applied by the user is released. When the trigger 98 is activated by pressure from the user to move the trigger 98 to the right, the lever 90 rotates about the pin point 92. The end at connection point 96 of lever 90 will move toward the distal end of the device 10 and the end at pivot point 94 will move in the direction of the proximal end of the device 10, thus causing the push rod 58 to move toward the proximal end of the device 10 and causing the ramp 60 of ride beneath the camming surface 44 and forcing the pre-clamp arm 26 into a closed position.

In the use of the device, the trigger 98 will be activated by the user to close the pre-clamp arm 26 while the device is being inserted through a trocar. Once a vein 62 that is to be ligated is located, the trigger 98 will be released, the pressure of spring 92 will force the trigger to move to the at rest position thereby rotating the lever 90 in a clockwise direction, retracting the push rod 58

5 toward the distal end of the device and allowing the pre-clamp arm 26 to open. The device 10 will then be manipulated so that a vessel 62 is captured between the upper surface of the fingers 32 and the lower surface of the arm 26 and toward the distal end of the depending nose 38 of the device. Once the vessel 62 is in position, the trigger 98 is activated by the user to cause a counter clockwise rotation of the lever 90 forcing the push rod 58 toward the proximal end of the device and causing the pre-clamp arm to rotate counter clockwise about the pin 52 and compress the vessel 62 in the manner shown in Fig. 7a. While holding the trigger 98 in the activated position, thus holding the pre-clamp arm 26 against the vessel 62 in the manner shown in Fig. 7a, the user of the device next activates the clip carrier/activator assembly 28 through the use of the activator key 106.

10 Key 106 is contained within the housing 88 of the pistol grip 12 in slots similar to the slots 100, 100' which retain the trigger 98. Key 106 is allowed to move between an at rest position as is shown in Fig. 3 and an activated position which is to the right of the at rest position. Spring 108 is connected at one end to stop 110 and at the other end to the inside of the key 106. Spring 108 is an expansion spring which tends to force the key 106 to the at rest position shown in Fig. 3.

15 20 25 Clip carriage actuation lever 112 is pivotally connected to the housing 88 at pivot point 114. Lever 112 extends down from pivot point 114 to a pivot connection 116 between the depending leg of the lever 114 and the key 106. Thus, when the key 106 is activated, moving it in the direction of the distal end of the device, the lever 112 is rotated in a counter clockwise direction about the pivot point 114. Moving the lever 112 in a counter clockwise direction about the point 114 causes the upper leg of the lever 112 to move generally toward the proximal end of the device. The upper portion of the lever 112 is connected to the clip carriage 64 via the link 118. The link 118 is pivotally connected at

one end 120 to the lever 112 and at the opposite end 122 to a boss 124 formed on the clip carriage 64. By the linkage just described, when the key 106 is activated, the clip carriage 64 moves toward the proximal end of the device 5 relative to the applicator sleeve 14 which at all times remains in a fixed position in relationship to the housing 88 of the pistol grip 12. By activating the key 106, through the operation of the clip actuation cam follower 126, the clip actuation push rod 84 is advanced relative to the clip 10 carriage 64 concurrently with the movement of the clip carriage 64 relative to the sleeve 14. The clip actuation cam follower is pivotally connected at 128 to the upper portion of the lever 112 so that when the upper portion of 15 the lever 112 moves in the direction of the proximal end of the device, the cam follower 126 rides over the clip actuation cam 130 causing the clip actuation cam follower 126 to rotate in a clockwise direction relative to the lever 112. The clip actuation push rod 84 is connected at its distal end 20 to the depending leg of the clip actuation cam follower 126 at 132. Thus, the clip actuation push rod 84 moves toward the proximal end of the device relative to the clip carriage assembly 64 and causes the depressor 74 to ride over the proximal end of the clip activation push rod, forcing the depressor upwardly against the pressure arm 22 of the 25 ligation clip 16.

As the mechanism described, the activation of key 106 advances the clip carriage assembly to the position shown in Fig. 7a. Continued pressure on the key 106 advances the clip actuation cam follower 126 over the clip actuation cam 130 so that the follower 126 disengages from the cam 130. A coil 30 spring (not shown) is provided at the pivot point 128 tending to force the cam follower 126 to rotate in a counter clockwise direction. Thus, as soon as the cam follower 126 releases from the cam 130 after it passes over the cam 130, 35 the spring about the pivot point 128 will force the cam follower 126 to rotate in a counter clockwise direction

5 thereby causing the clip actuation push rod 84 to retract toward the distal end of the device. When the clip actuation push rod 84 attracts toward the distal end of the device, the pressure of the depressor 74 is relieved from the underside of the pressure arm 22 and the pressure arm 22 closes on the vessel 64, capturing the vessel 64 between the underside of the pressure arm 22 and the top side of the base 20 of the clip 16.

10 To release the clip 16 from the device, additional pressure is applied to the key 106 thus forcing the clip assembly 64 to advance further in the direction of the proximal end of the device relative to the stationary sleeve 14, forcing the wings 66 beyond the proximal end of the sleeve 14 so that the wings 66 may fan open and release the clip 16.

15 In order to return the device to the at rest or ready position for insertion of another clip, pressure on the key 106 is released. Spring 108 forces the key 106 toward the proximal end of the device thus rotating the lever 112 about the point 114 in a clockwise direction. The entire device is then reset. The cam follower 126 is allowed to pass back to the ready position by virtue of the pivotal connection of the cam 130 to the housing 88. The cam 130 is pivotally connected at 134 to the housing 88 and the cam 130 has a ramp 136 formed on the surface of the cam 130 that faces the housing 88 of the grip 12 shown in Fig. 3. The cam 130 has a spring (not shown) tending to force the cam 130 against the housing 88 as shown in Fig. 3. When the cam follower 26 decides to return to the at rest position, it will ride against the ramp 136 causing the cam 130 to rotate about the pivot point 134 and slip up slightly to allow the cam follower 126 to pass between the cam 130 and the housing 138. Once the cam follower 126 clears the cam 130, the spring will rotate the cam 130 back to the ready position as is shown in Fig. 3.

30 Relieving the pressure on the key 106 also causes the

clip cartridge 64 to retract toward the distal end of the device into the ready position.

A locking lever 136 is also provided on the lever 112 and pivotally connected to the lever 112 at point 138. The locking lever 136 fits over the lever 90 so that when the key 106 is in the at rest position and the lever 112 is rotated into its clockwise most position, the locking lever 136 will hold the lever 90 in the position that would occur if the trigger 98 were depressed. Thus, the push rod 58 is advanced forward to cause the pre-clamp arm 26 to be closed. This locking lever allows the device to be inserted through a trocar without the user having to hold the trigger 98 in an activated position. In operation, once pressure is applied to the key 106, the pressure of the locking lever 136 on the lever 90 is released allowing the spring 102 to push the trigger 98 toward the proximal end of the device thereby retracting the push rod 58 and allowing the pre-clamp arm 26 of the device to open. Once the pre-clamp arm of the device is open, the pre-clamping pressure on a vessel 62 is created by activation of the trigger 98, thus forcing the push rod 58 toward the proximal end of the device and causing the pre-clamp arm to close against the fingers 32.

Once a clip has been applied in the manner described, a second clip is loaded into the ready position from the clip carriage 64 by the mechanism illustrated in Figures 13A and 13b forcing the ligation clip 16 to advance toward the proximal end of the device.

The mechanism shown in Fig. 13A and 13b is mounted in the pistol grip 12 directly adjacent link 118. The mechanism shown in Figs. 13A and 13b is not illustrated in Fig. 3 for purpose of clarity. However, the additional mechanical structure shown in Figs. 13A and 13B are mounted directly above link 118 and in engagement therewith.

Referring now specifically to Figs. 13A and 13B, there is illustrated a clip pushrod 154 which is slidably mounted within the pistol grip 12 and permitted to move in a lineal

5 direction along its length. The proximal end 156 of the clip pushrod 154 will be in engagement with the rear most ligation clip 16 in the magazine of clips positioned in the carriage passageway. Movement of the clip pushrod 154 toward the proximal end of the device will force the forward most ligation clip 16 into the carriage assembly.

10 The controlling mechanism for advancing the ligation clips is provided by link 118 which has teeth 119 on the upper edge thereof in mating engagement with teeth 151 on the outer perimeter of the one-way ratchet clutch 150. The cog wheel 152 is mounted to rotate with the one-way ratchet clutch 150 and is coaxially aligned with the one-way ratchet clutch 150. The cogs 153 on the cog wheel 152 engage the cog ports 155 in the clip pushrod 154. In operation, as can be seen from Fig. 13B, upon forward motion of link 118 as is shown by the arrow in Fig. 13B, the one-way ratchet clutch 150 will rotate counter clockwise, but cog wheel hub 158 will not rotate because the teeth 159 protruding from the cog wheel hub 158 will ratchet over the ramped ratchet teeth 160. 15 However, when the link 118 moves in the reverse direction, the engagement between the teeth 119 on the link 118 and the teeth 151 will cause the one-way ratchet clutch 150 to rotate in a clockwise direction, causing the tooth face 161 to engage the teeth 159 and rotate the hub 158 in a clockwise direction. Fig. 13B is viewed from the bottom of the assembly shown in Fig. 13A; thus, when viewed from the top, the only rotational movement of the cog wheel 152 will be in a counter clockwise direction upon the movement of the link 118 toward the distal end of the device. When the link 118 moves toward the proximal end of the device, the ratcheting mechanism will cause the cog wheel 152 to remain stationary. 20 25 30

35 The operation of the assembly shown in Figs. 13A and 13B will thereby control the movement of a clip 16 from the ready position into the carriage assembly as follows: when the device is being reset, link 118 moves to the rear, causing cog wheel 152 to rotate, advancing clip pushrod 154 to load

5 a new clip into the clip carriage. When the mechanism is activated and the link 118 moves forward, the cog wheel 152 remains stationary so that the clips 16 in the clip magazine do not advance. Thus, the mechanism as described retains the
clips in the ready position until the mechanism is activated by the retracting carriage assembly 64 rotating the cog wheel 152 and advance the clip pushrod 154 so that a single clip moves forward and is permitted to advance into the carriage assembly.

0 As can be seen from Fig. 3, the device of the present invention can be used in a number of different procedure and the applicator sleeve 14 and related assemblies can be removed from the pistol grip and replaced with a clean sterile sleeve 14 for a second operative procedure with a new patient. The device is provided with a hinged cover 140 which is hinged to the housing 88 at 142. The closure mechanism 140 can be held in place by any convenient safety latch 144 (see Fig. 1). The housing is provided with upper and lower recesses 146 and 148 and the sleeve 14 can be provided with bosses (not shown) that fit within the upper and lower recesses 146, 148 to stabilize the position of the applicator sleeve 14 in relationship to the pistol grip 12. The pivotal connections 94, 122 and 132 can be designed so that the pins will slidably engage within the openings to permit the applicator sleeve 14 and related parts to be lifted from the pistol grip 12 and replaced by an applicator sleeve loaded with a fresh ligation clip 16. To make this replacement, it is necessary that the face of the pistol grip 12 be removable from the pistol grip and have means for connecting the face onto the pistol grip 12 in a fixed relationship. Any convenient latching mechanism can be provided to connect the face of the pistol grip onto the body of the pistol grip 12.

10 Thus, although there have been described particular 15 embodiments of the present invention of a new and useful "Low Profile Tool for Applying Spring Action Ligation Clips", it

5 is not intended that such references be construed as limitations upon the scope of this invention except as set forth in the following claims. Further, although there have been described certain dimensions used in the preferred embodiment, it is not intended that such dimensions be construed as limitations upon the scope of this invention except as set forth in the following claims.

CLAIMS

What I claim is:

1. A tool for facilitating application of a ligation clip, the device comprising:

- 5 a. a housing;
- b. a means for holding a ligation clip, the means being movable through the length of the housing and beyond the distal end of the housing;
- 10 c. a pre-clamp means movable within the housing and beyond the distal end of the housing;
- d. a means to cause the pre-clamp means to extend between an open and a closed position;
- 15 e. a means to open a ligation clip; and,
- f. a means to cause the means holding the ligation clip to release the ligation clip after clamping a vessel or duct.

20 2. A device for facilitating application of a ligation clip as in claim 1, wherein the means for holding the ligation clip comprises a slot positioned longitudinally within the housing and having a shape complementary to the shape of the ligation clip.

25 3. A device for facilitating application of a ligation clip, the device comprising:

- 25 a. a housing
- b. a channel assembly slidably mounted in the housing;
- 30 c. a means for fixedly holding a ligation clip, such means positioned within the channel assembly;
- d. a first mechanical actuator means capable of lateral translation within the channel assembly;
- 35 e. a lever means rotatably positioned within the channel assembly and having a camming surface upon which the first mechanical actuator means is slidably extensible causing a rotational movement of the lever which causes a middle prong of the ligation clip to open;

5 f. a pre-clamp means positioned outside of and adjacent to the channel assembly and pivotally connected to the housing in a position adjacent to the channel assembly such that a distal end of the pre-clamp means is capable of temporarily clamping a vessel or duct in a stationary position and a proximal end of the pre-clamp means has a cammed surface; and

10 g. a second mechanical actuator means capable of lateral translation outside of the channel assembly and slidably extensible and having a distal end of the second mechanical actuator means positioned in relation to the cammed surface of the pre-clamp means such that the pre-clamp is capable of movement in a direction which allows the pre-clamp to open and close.

15 4. A device for facilitating application of a ligation
clip as in claim 3, wherein the pre-clamp means comprises a
yoke-shaped pre-clamp means having a slot longitudinally
positioned in the center therein.

20 5. A device for facilitating application of a ligation
clip as in claim 3, wherein the pre-clamp means comprises a
single arm positioned longitudinally and off-center from the
fixedly held ligation clip.

25 6. A device for facilitating application of a ligation
clip as in claim 3, wherein the means for fixedly holding a
ligation clip comprises a first longitudinally positioned arm
having a slot and a second longitudinally positioned arm
having a slot, such that the first arm is spring biased away
from the second arm to allow for release of the ligation clip
following ligation of a vessel or duct.

30 7. A device for facilitating application of a ligation
clip as in claim 1, wherein the channel assembly comprises:

a. a base positioned longitudinally, upon which the ligation clip is positioned;

35 b. a pivot means set within the lower portion of the channel assembly to which the lever arm is pivotally secured;

c. a groove located longitudinally within the lower portion of the channel assembly; and,

5 d. a first mechanical actuator/push bar slidably positioned within the groove, such that the first mechanical actuator/push bar is slidably coupled to a camming surface located on the lower portion of the lever arm.

8. A method of ligating a vessel or duct during surgery comprising the steps of:

10 a. placing a ligation clip applier which carries a ligation clip ready to be applied to such vessel or duct;

b. positioning such vessel or duct within the pre-clamp means;

15 c. closing such pre-clamp means around such vessel or duct to effectuate a compression of the vessel or duct;

d. opening the ligation clip by moving a first mechanical actuator means;

20 e. positioning the opened ligation clip around the compressed vessel or duct by slidably moving the channel assembly, which holds the ligation clip, distally toward the vessel or duct;

f. closing the ligation clip around the compressed vessel or duct by moving the first mechanical actuator means, resulting in ligation of the vessel or duct; and,

25 g. releasing the ligation clip and the vessel or duct which the ligation clip is ligating.

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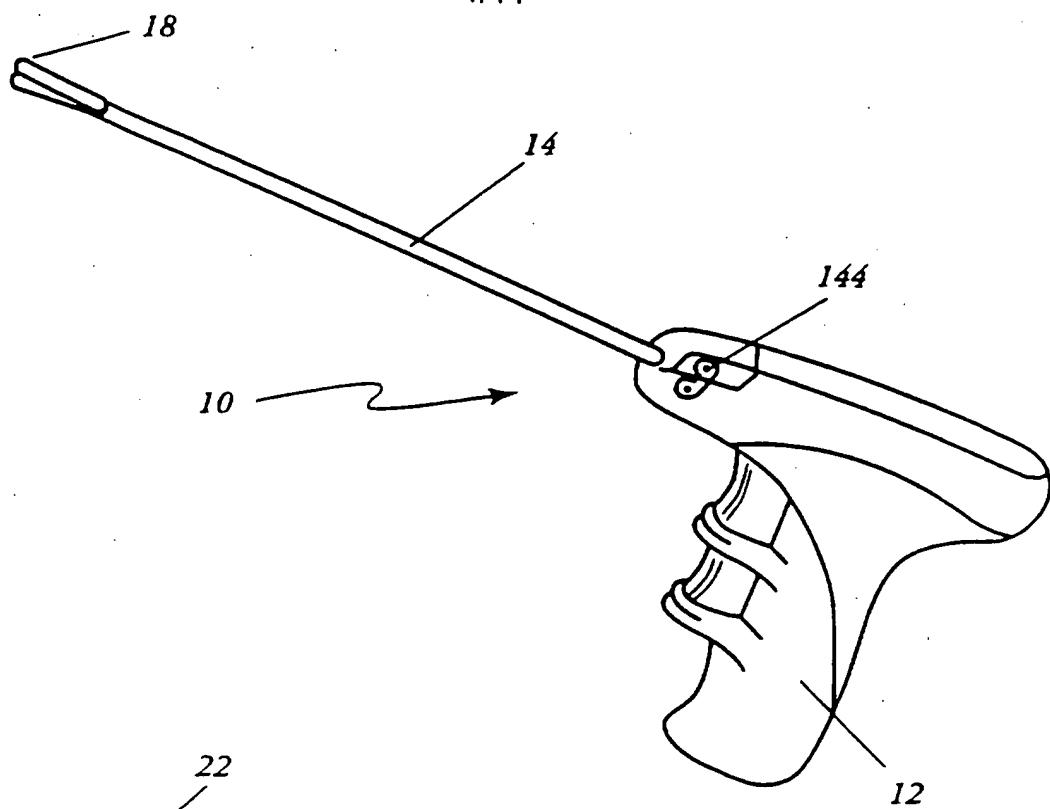


FIG. 1

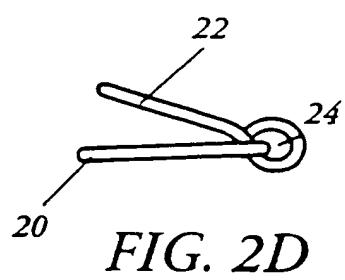


FIG. 2D

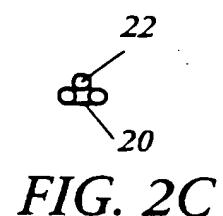
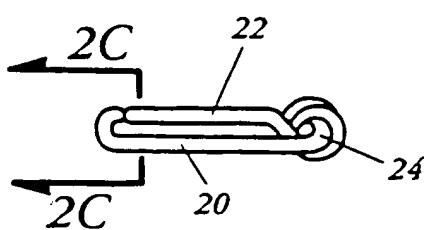


FIG. 2C

FIG. 2B

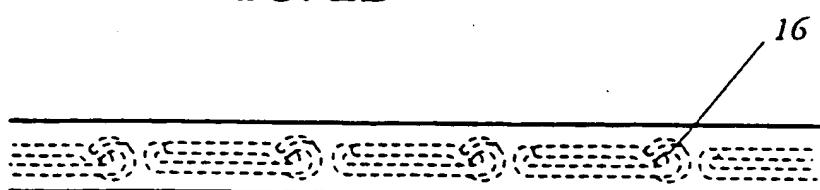


FIG. 2A

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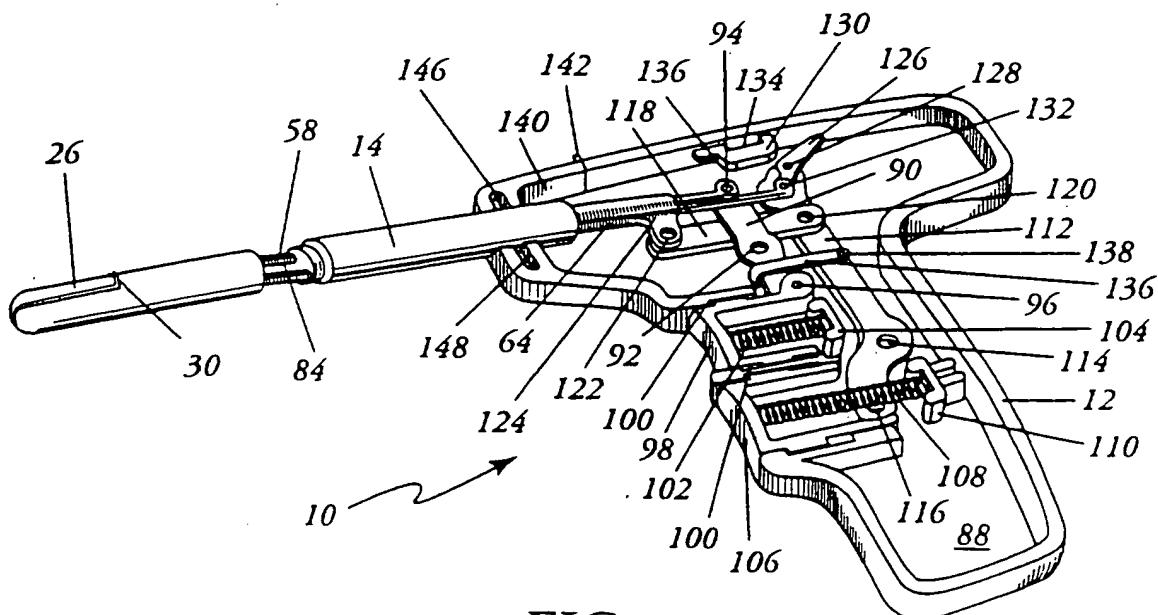


FIG. 3

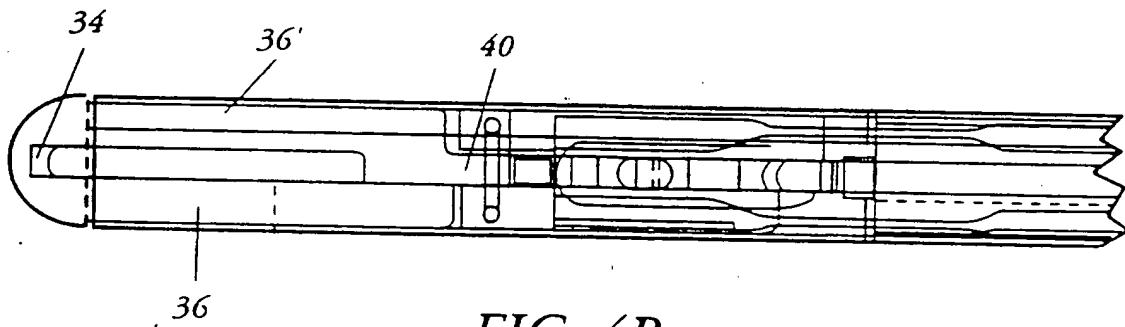


FIG. 4B

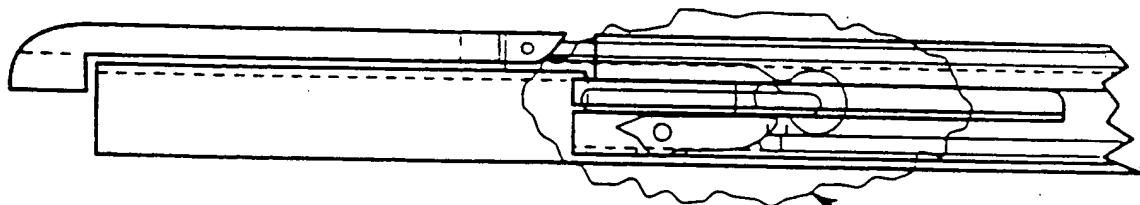


FIG. 4A

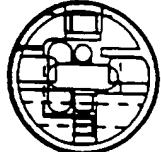


FIG. 4C

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FIG. 5A

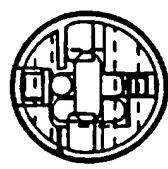
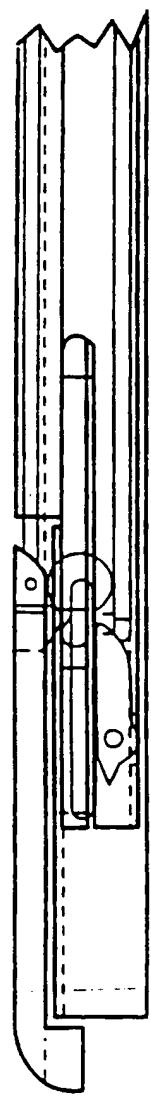
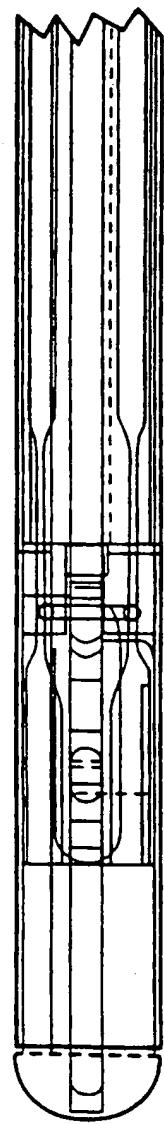


FIG. 5C

FIG. 5B



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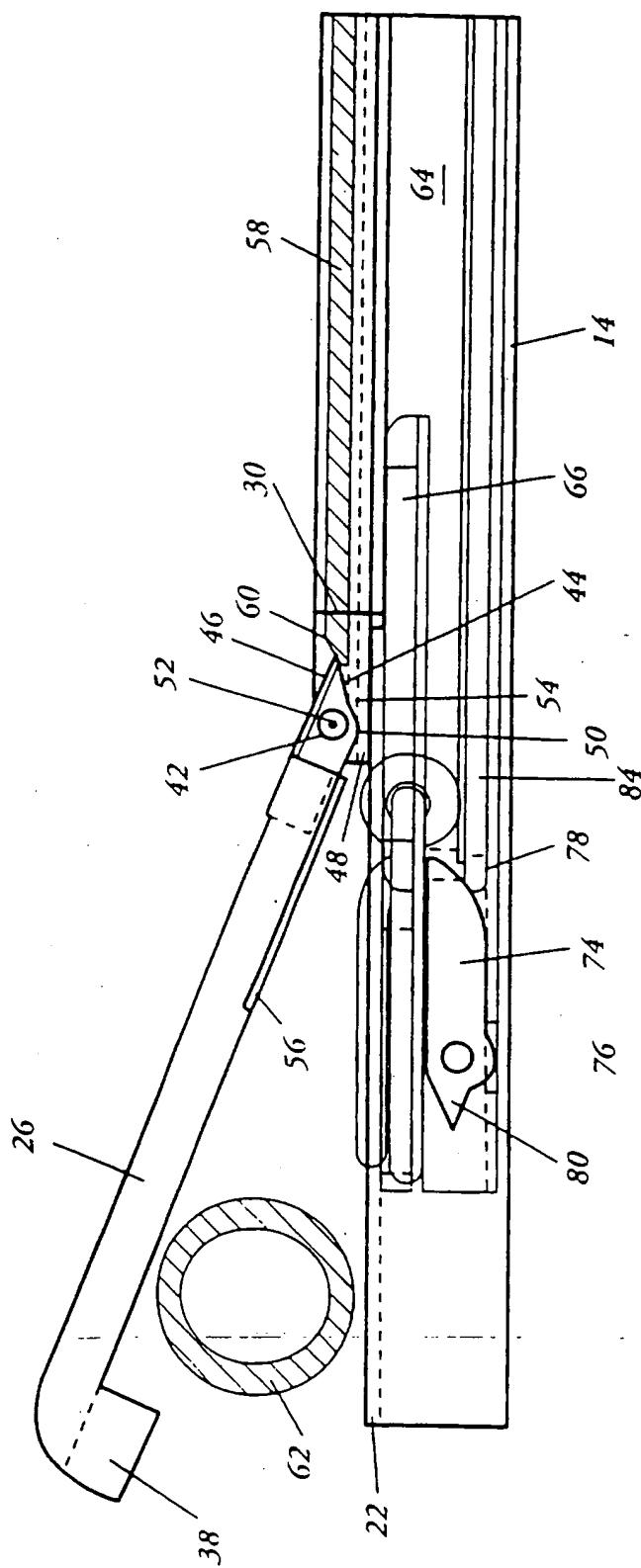


FIG. 6A

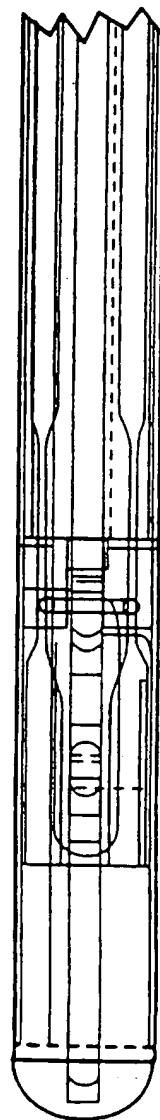


FIG. 6B

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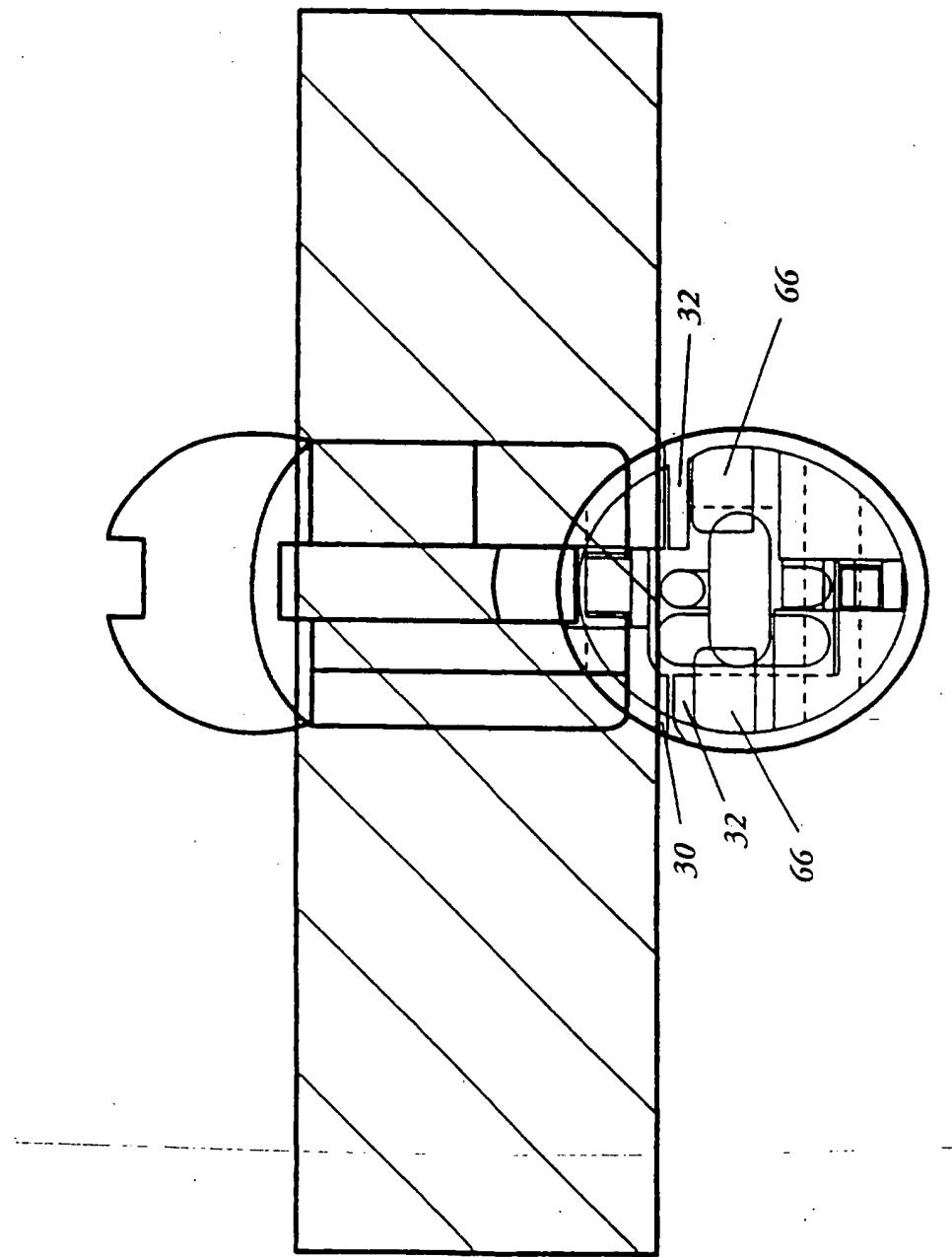


FIG. 6C

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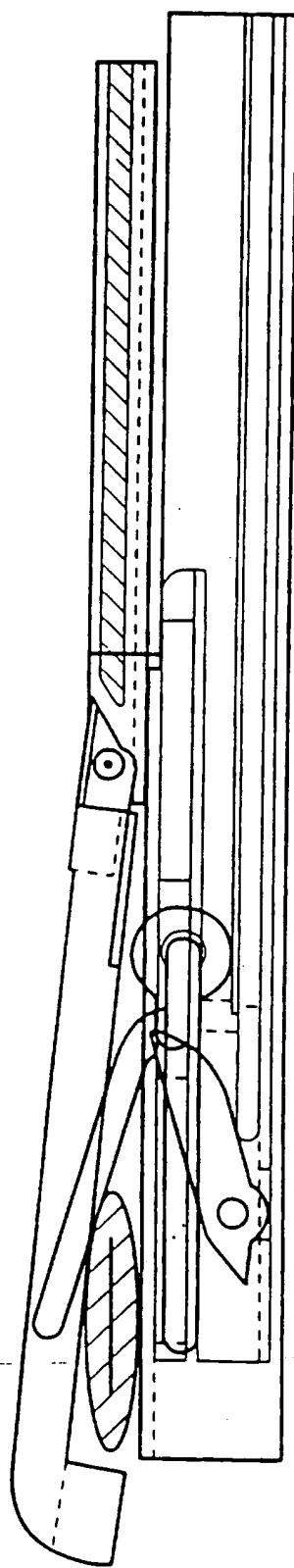


FIG. 7A

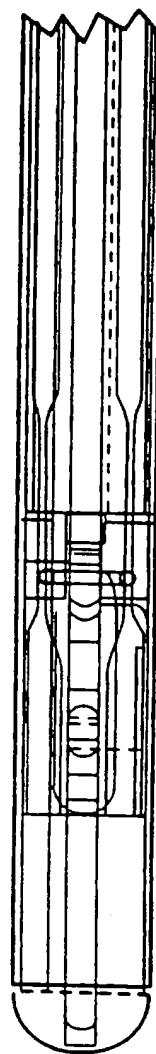


FIG. 7B

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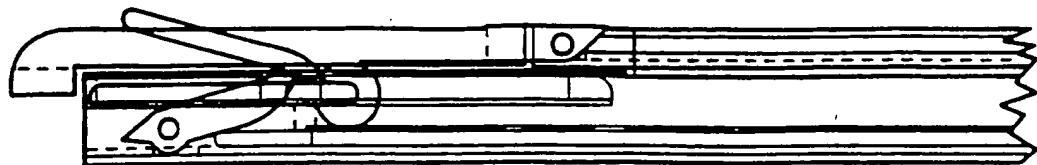


FIG. 8A



FIG. 8B



FIG. 8C

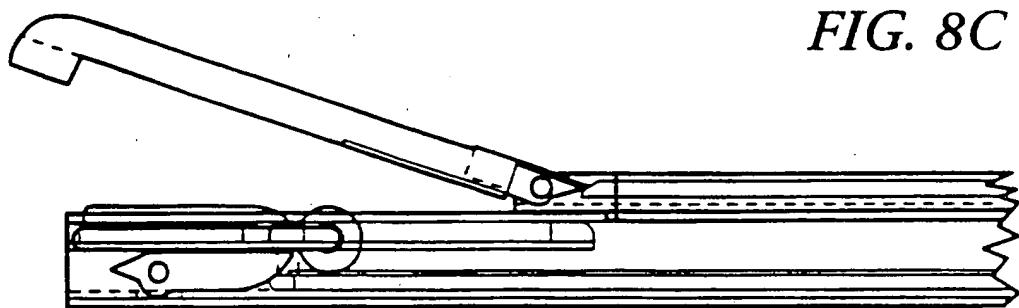


FIG. 9A



FIG. 9B

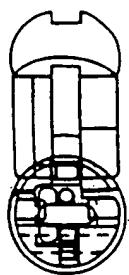


FIG. 9C

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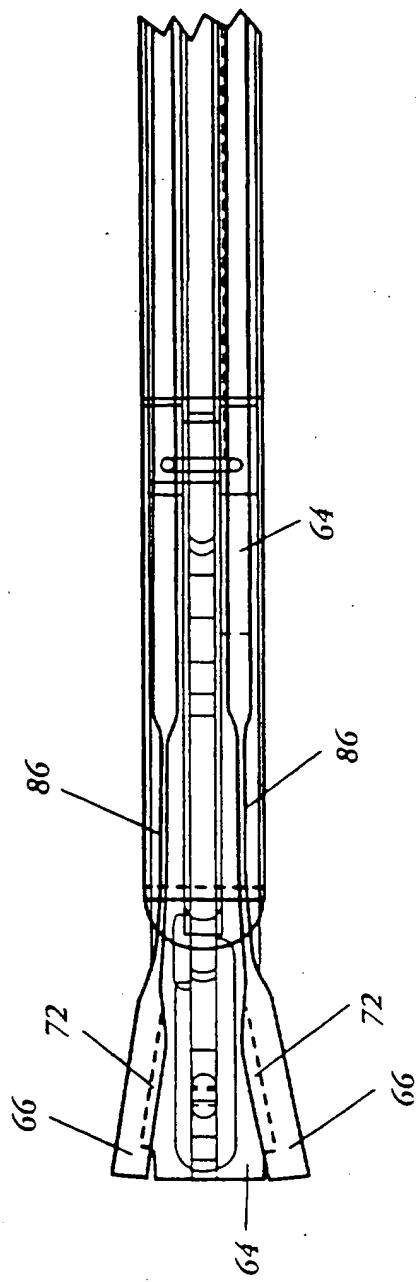


FIG. 10B

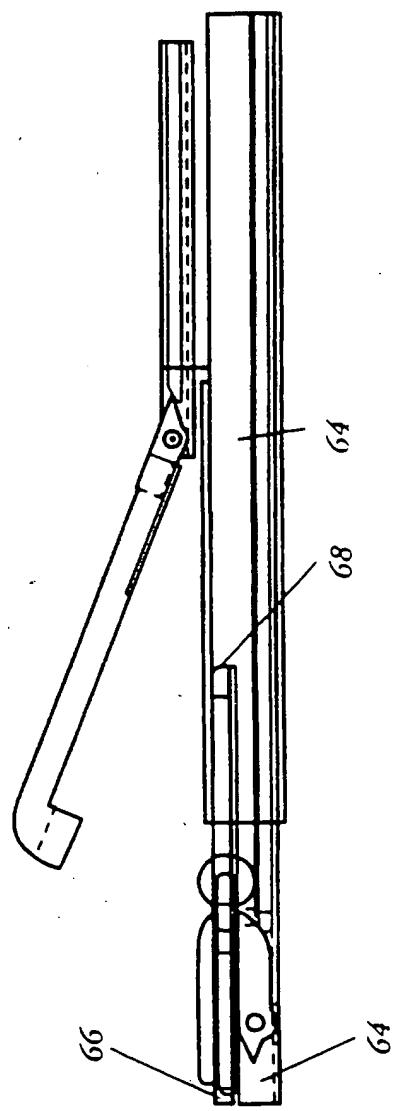


FIG. 10A

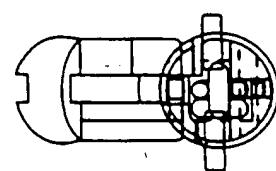


FIG. 10C

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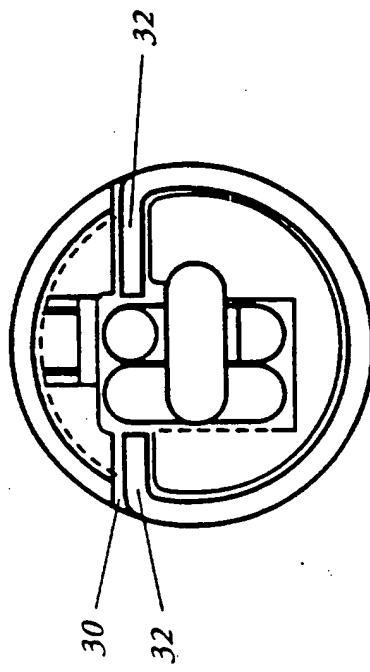


FIG. 11

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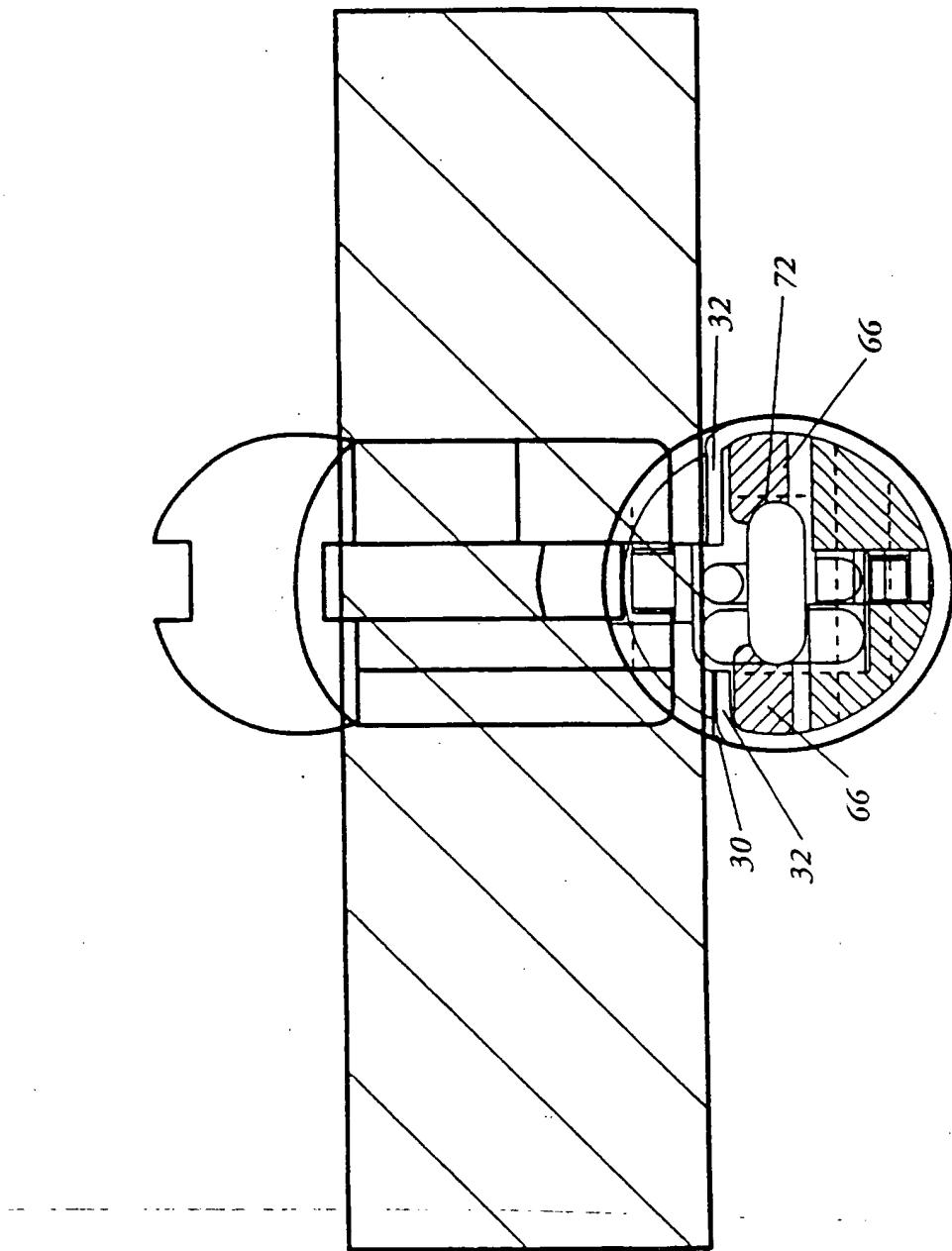


FIG. 12

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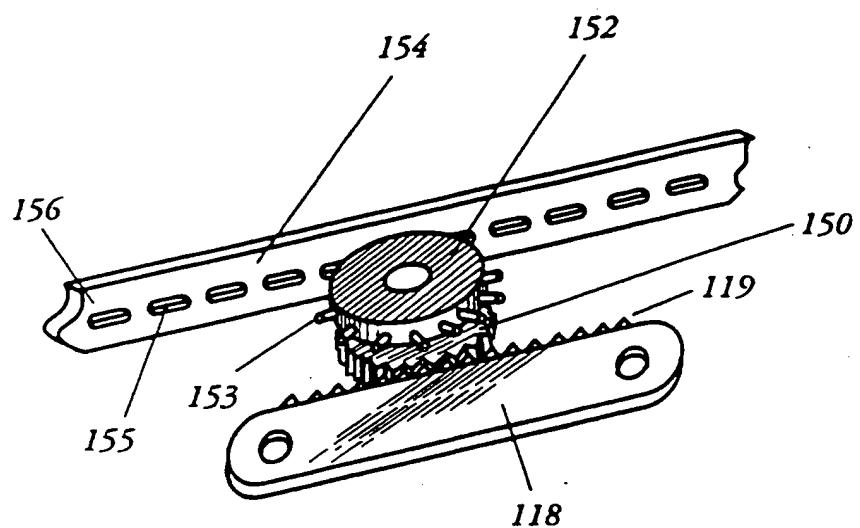


FIG. 13A

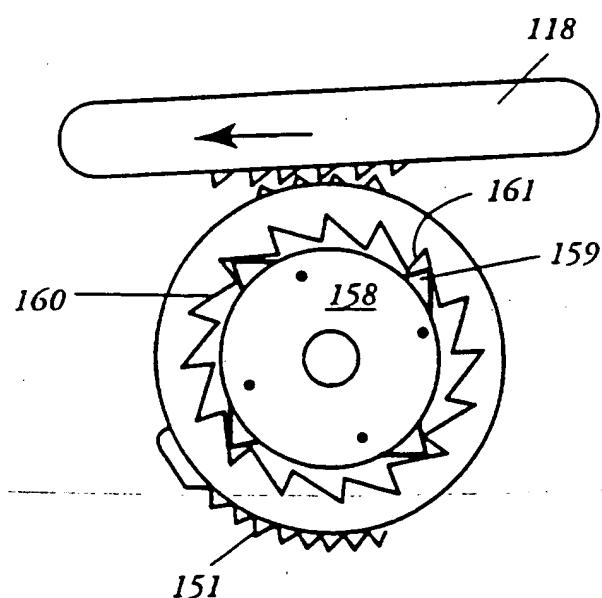


FIG. 13B

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US95/12895

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/128

US CL :606/142

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 29/243.56; 606/142, 143

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
X	US, A, 5,342,373 (STEFANCHIK ET AL.) 30 August 1994, see entire document.	1, 2, 8

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*'A' document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
*'E' earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
*'L' document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reasons (as specified)	"&"	document member of the same patent family
*'O' document referring to an oral disclosure, use, exhibition or other means		
*'P' document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

11 DECEMBER 1995

Date of mailing of the international search report

11 JAN 1996

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